REMARKS

Claims 1, 2-5, 7, 20, 29, 44, 46, 59, 61 and 62 stand rejected under 35 USC § 102(e), as being anticipated by Feld, U.S. Patent Publication No. 2004/0002626. Claims 1, 5, 7, 13-15, 19, 20, 26, 29, 34, 43, 44, 60, 68-71, 75, 78 and 89 stand rejected under 35 USC § 102(e) as being anticipated by Ferrazzi, U.S. Patent Publication No. 2003/0158570. Claim 40 stands rejected under 35 USC § 103(a) as being unpatentable over Feld in view of Stevens, U.S. Patent No. 6,125,852. Claims 36 and 80 stand rejected under 35 USC § 103(a) as being unpatentable over Ferrazzi in view of Cloud, U.S. Patent No. 5,184,482. Claims 6, 8-12, 16, 18, 21-25, 27-28, 30-33, 35, 37-39, 41-42, 45, 47-58, 63-67, 72-74, 76-77, 79 and 81-88 were previously cancelled. Claim 19 is cancelled by this amendment. Thus, claims 1-5, 7, 13-15, 17, 20, 26, 29, 34, 36, 40, 43, 44, 46, 59-62, 68, 69, 71, 75, 78, 80 and 89 remain at issue.

Rejections over Feld, U.S. Patent Publication No. 2004/0002626

Claim 1 is directed to an apparatus implantable in a heart ventricle comprising a frame configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded state corresponding to a desired end diastolic diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle. Assisting means are operatively associated with the frame for mechanically assisting movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole. Means are operatively associated with the frame for limiting the ventricle to a select end diastolic internal diameter.

A means operatively associated with the frame for limiting the ventricle to a select end diastolic internal diameter is depicted in Fig. 7 and in this example comprises the flexible cables 81, 82 terminated with loops 83 and knots 88 that are firmly retained against member 30, 32 and 31, 33, respectively. As set forth in the Specification at page 13, lines 10-15: "Optional flexible cables 81, 82 serve to restrict the maximum diameter of the device, and hence limit the end diastolic diameter of the heart." Thus, the flexible cables absolutely prevent expansion of the ventricle during diastole beyond a select diameter.

Feld does not teach means operatively associated with a frame for limiting the ventricle to a select end diastolic internal diameter. Rather, Feld teaches an elastic arm or extension 12 (see Figs. 10A and 10B) which is intended to at some point overcome diastolic expansion of the

heart and initiate systole. However, by definition the elastic members 12 of Feld cannot limit the ventricle to a *select* end diastolic internal diameter. In other words, the elastic property of the elastic arm or extension 12 means that the end diastolic internal diameter will vary as a function of force applied to the elastic arm. Thus, as the force increases the end diastolic internal diameter will increase. This is to be contrasted with the structure illustrated in claim 1, which provides an absolute stop to the end diastolic internal diameter of the ventricle. Thus, for at least this reason, Feld cannot anticipate claim 1. Claims 2-5, 7, 13-15, 17, 20 and 26 are each dependent from claim 1 and are not anticipated by Feld for at least the reasons set forth above with regard to claim 1.

Claim 29 is directed to a method of treating cardiac disease comprising surgically accessing a ventricle and inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole. The apparatus is configured to limit the ventricle to a select end diastolic internal diameter. The device is attached to a portion of myocardium defining an inner circumferential periphery of the ventricle.

Claim 29 is similar to claim 1 in that it recites inserting an apparatus configured to limit the ventricle to a select end diastolic internal diameter. As discussed above, Feld does not teach any structure for limiting the ventricle to a *select* end diastolic internal diameter. Rather, Feld teaches elastic elements that will allow the ventricle to assume varying end diastolic internal diameters which are a function of the diastolic force applied to the ventricle. Thus, Feld cannot anticipate claim 29. Claims 34, 36, 40 and 43 are each dependent from claim 29 and are thus not anticipated for at least this reason.

Claim 44 is directed to an apparatus implantable in a heart ventricle comprising a bistable element configured to engage an inner circumferential periphery of a ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and an end diastolic diameter, respectively.

As is clear in the Specification, the recited bistable element requires having a stable expanded condition as illustrated in Fig. 1 and a stable contracted position as illustrated in Fig. 4. See the description beginning at page 11, line 22 – page 12, line 25. Referring specifically to page 14 beginning at line 26, the Specification explains:

"As discussed above, the longitudinal bands of the cage are formed so as to be able to shift between contracted and expanded stable states, thus making the cage bistable. The bands, which are anchored to the myocardium, are sensitive to the lateral forces of a contracting left ventricle during systole, initiating movement in the same direction toward an end desirable diameter. The contracting and, therefore, shortening left ventricle also applies a powerful axial force to the longitudinal axis of the device. These two forces working in concert, generate a lateral displacement of the elements of the device causing the device to spring into the opposite bistable direction, or contracted state, releasing stored energy, and creating a powerful pumping force. The changed resting state of the longitudinal bands in the contracted state are sensitive to the lateral forces generated by the diastolic ventricular relaxation, initiating movement of the longitudinal elements in the same direction toward the opposite bistable state. The relaxing and elongating ventricle facilitates the movement of the longitudinal element in the direction of toward the expanded bistable state. Once displaced a select amount, the bistable element springs toward the expanded state. The corresponding release of stored energy augments the ventricular wall expansion of diastole and thereby creates a "sucking" force to enhance left ventricular filling and restore optimal diastolic function. Furthermore, the longitudinal structure of the device applies a restrictive force to fix the end-diastolic dimensions of the left ventricle to a more optimal size, shape and volume and, thereby, reduces myocardial wall stress during early systole. Optional transverse cables with loops retained firmly against opposing longitudinal bands restrict end diastolic diameter of the heart."

As discussed above, Feld teaches only elastic members for providing ventricular assist. The elastic members have only a *single* stable position and are not "bistable" as that term is used in the claims and as that term is described in great detail in the Specification, as illustrated above. Thus, Feld cannot anticipate claim 44. Claims 46 and 59-60 are dependent from claim 44 and thus cannot be anticipated for at least this reason as well.

Claim 61 is directed to a method of augmenting systolic contraction and diastolic relaxation of a heart ventricle and recites providing a bistable element configured to engage an inner circumferential periphery of a ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and end diastolic diameter, respectively. As set forth above, Feld does not teach a bistable element. Thus, claim 61 cannot be anticipated by Feld.

Claim 62, which is dependent from claim 61, further recites limiting the expanded stable state of the bistable element to a select diameter. As discussed above with respect to claim 1,

Feld does not teach this element either. Thus, for this reason as well, claim 62 cannot be anticipated by Feld.

Rejections over Feld, Ferrazzi, U.S. Patent Publication No. 2003/0158570

As set forth above, the various independent claims each include in some form a limitation directed to means operatively associate with a frame for limiting the ventricle to a select end diastolic internal diameter or the frame comprising a bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and end diastolic diameter, respectively. As will be discussed below, like Feld, Ferrazzi fails to teach either of these limitations. Thus, like Feld, Ferrazzi fails to anticipate the various claims.

Regarding claim 1, Ferrazzi teaches a plurality of elastic bands 6, 7 and 8. In the words of the Specification of Ferrazzi:

> "As already said, the devices are plastic in the direction of the axis of the ventricle (see Figs. 7 and 8) and elastic in the direction of the ventricle radius: this leads to an active diastolic expansion in which the resilience of the device under endoventricular pressure, allows its radial dilation to a predetermined useful extent and the simultaneous accumulation of elastic energy: at its maximum load the device returns to its resting dimensions, thus operating an active systolic return as a result of its elastic force.
>
> The function of elasticity illustrated by the devices is not linear because, in the diastolic phase, they must oppose little resistance against expansion; the elasticity of the material must diminish in an inverse relationship with endoventricular pressure in such a way as to ensure that the device opposes greater resistance to dilation as it expand towards its maximum diameter, which coincides with the maximum value of end-diastolic pressure."

Ferrazzi, ¶77 and 78.

Thus, Ferrazzi, like Feld, clearly teaches an elastic resistance to diastolic expansion of the ventricle and thus cannot constitute "means operatively associated with the frame for limiting the ventricle to a *select* end diastolic internal diameter. In other words, the end diastolic internal diameter of Ferrazzi, line Feld, will be a function of the diastolic force applied to the ventricle. It should be noted that the cross members 10 of Fig. 10 are elastic elements (see ¶81) and thus cannot constitute limiting means. Thus, Ferrazzi cannot anticipate claim 1 or claims 5, 7, 13-15, 20 or 26, which are dependent therefrom. Likewise, Ferrazzi cannot anticipate independent claim 29 or claims 34 or 43, which are dependent therefrom.

Claim 44 recites a bistable element as described above in detail with respect to the rejections over Feld. The elastic members disclosed in Ferrazzi are not bistable, but instead have a single stable position. Thus, claim 44 and claim 60, which is dependent from claim 44, cannot be anticipated by Ferrazzi.

Claim 68, like claim 1, recites means operatively associated with the resilient band for limiting the ventricle to a select end diastolic internal diameter. Because Ferrazzi does not teach this limiting means, claim 68 cannot be anticipated by Ferrazzi. Likewise, claims 69-71 and claim 75, which are dependent from claim 68, cannot be anticipated by Ferrazzi.

Claim 78 is directed to a method of treating cardiac disease and includes providing a resilient band having at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band and means for limiting axial stretching of the resilient band to a select diameter. As discussed above, Ferrazzi does not include such limiting means. Thus, claims 78 and 89, which is dependent from claim 78, cannot be anticipated by Ferrazzi.

Rejections Under 35 USC § 103(a)

Claim 40 stands rejected over Feld in view of Stevens, U.S. Patent No. 6,125,852.

Stevens is cited for the proposition that it is known in the art to perform a ventricular reduction on a congestive heart failure patient in order to reshape the enlarged heart to a normal size. However, Stevens does not teach or suggest the structure for limiting the ventricle to a select end diastolic internal diameter recited in claim 29 and thus claim 40 is not obvious over a combination of Feld in view of Stevens.

Claims 36 and 80 stand rejected under 35 USC § 103(a) as being unpatentable over Ferrazzi in view of Cloud, U.S. 5,184,482. Claims 36 and 80 each include the limitation of limiting means as discussed above. Cloud does not teach such a limiting means, nor does Ferrazzi. Thus, claims 36 and 80 cannot be anticipated by a combination of Ferrazzi and Cloud.

Conclusion

For the foregoing reasons, reconsideration and withdrawal of the rejection of the pending claims and prompt issuance of a Notice of Allowance are respectfully requested. If it would be

helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

Respectfully submitted,

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